

## **R E M A R K S**

The applicants acknowledge the Examiner's comprehensive Office Action with appreciation. The Office acknowledges receipt of the Request for Continued Examination (RCE) and submission of April 19, 2004. The Office does not acknowledge the Applicants' Preliminary Amendment of June 3, 2004. Claims 1-13 and 15-17 remain under consideration. The Office raises an obviousness rejection under 35 USC § 103(a) and a double-patenting rejection.

The Office does not acknowledge the Applicants' Preliminary Amendment of June 3, 2004, in which treatment of IBS was added to Claim 1. Support for this amendment can be found in the instant specification at pages 10 and 21. The Applicants submit that the Image File Wrapper System on the USPTO website shows that the Preliminary Amendment was present in the Image File Wrapper System on June 7, 2004. The Applicants respectfully request acknowledgement and entry of the Preliminary Amendment. Moreover, the Applicants are entitled to a "first pass" consideration of the subject matter of this amendment. The Applicants cannot be responsible for the Office oversight of this amendment.

Claims 1-13 and 15-17 are rejected for obviousness under 35 USC § 103(a) based on Gold, et al. (WO 99/01416) in view of Ravelli, et al., Sullivan, et al., or Wilde, et al. It is the position of the Office that Gold, et al. disclose that the same 1-aminoalkylcyclohexane compounds as those of the instant invention are "useful in a pharmaceutical composition and method for the treatment of CNS disorders or a living animal for alleviation of a condition which is alleviated by an NMDA receptor antagonist." The Office therefore draws the conclusion that Gold, et al. teach broad usefulness of the instant compounds in methods of treatment of pathological conditions such as CNS disorders, even though the specific disorders of the instantly claimed method are not disclosed and even though Gold, et al. specifically disclose treatment of CNS disorders "resulting from disturbances of glutamatergic transmission." The Office goes on to conclude that since additional cited references show that emesis, cerebellar tremor and appetite disorders are known CNS disorders, it would have been obvious to one skilled in the art that the instant

compounds would have beneficial therapeutic effect in the instantly claimed method based on the disclosure of Gold, et al.

Gold, et al. disclose a method of treatment directed to “a wide range of CNS disorders which involve disturbances of glutamatergic transmission.” Sullivan, et al. disclose that the regulation of appetite is a “complex process” and that anorectic drugs which act by central mechanisms have limited effectiveness. The Wilde, et al. reference is a review of Ondansteron, a selective 5-HT<sub>3</sub> receptor antagonist. Wilde, et al. discuss various CNS-related disorders; however these conditions are associated with the 5-HT<sub>3</sub> receptor based the statement, “The wide distribution of 5-HT<sub>3</sub> receptors in the body and the role of these receptors in disease have provided the rationale for investigation of Ondansteron in novel applications.” Ravelli, et al. disclose that vomiting is common in children with disorders of the CNS. This reference provides little insight into the CNS receptors associated with this condition.

Thus, the Office has cited Gold, et al. which discloses that the instant compounds are glutamatergic antagonists useful for treating disorders of the glutamatergic system and multiple additional references which speak to different compounds as serotoninergic antagonists. The Applicants submit that the Office has provided no basis for combining these references, consequently, the rejection is without basis in law or fact to make out an obviousness rejection. The Office has not demonstrated that it would have been obvious to one skilled in the art to treat a CNS condition associated with the 5-HT<sub>3</sub> receptor with compounds which are known to act through a glutamatergic mechanism. Reconsideration and withdrawal of the obviousness rejection are respectfully requested.

Claims 1-13 and 15-17 are provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over Claims 5 and 7 of copending Application Serial No. 10/288,819. It is the position of the Office that although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to a method-of-treating a list of conditions treatable by a 5-HT<sub>3</sub> antagonist, which includes the conditions treatable in the instant application with the **same compound** as in the instantly claimed

method. However, the Applicants submit that the compounds of US Serial No. 10/288,819 do not include aminocyclohexane derivatives in which all of the substituents are alkyl groups. Therefore, US Serial No. 10/288,819 **does not involve the same compounds** as the instant application. Moreover, US Serial No. 10/288,819 stems from a November 6, 2002 filing date whereas the instant application arises from a June 20, 2000 filing date. Therefore, the instant application cannot read on the later application. Reconsideration and withdrawal of the double-patenting rejection are respectfully requested.


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Accordingly, entry of the present amendment, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,  
THE FIRM OF HUESCHEN AND SAGE

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**THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.**